COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY

December 18, 2020

Webex Information

Call in Number: 1-203-607-0564 or toll free 1-866-692-3580

Access Code: 178 674 7221

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Yulanda Kiner, Phone: 617-624-5848 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item	Page	Contact
8:00	**I**	**CALL TO ORDER**		K. Tanzer
8:05	**II**	**APPROVAL OF AGENDA**		
8::10	**III**	**APPROVAL OF BOARD MINUTES** • Draft of December 6, 2020 Regular Session Minutes		
8:12	**IV**	**APPLICATIONS** • The Hilsinger Company (WD450)-Transfer of Ownership • Omnicare of Northern MA – Renovation • Oakmontscript Pharma – Wholesale Distributor		
8:30	**V**	**FLEX** • Pharmacy issues related to Covid-19 and the state of emergency		D. Sencabaugh
8:40	**VI**	**POLICIES** • Policy 2020-14: COVID-19 Testing • Policy 2020-15: Licensee Scope of Practice		

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<tr><td>9:10</td><td>VIII</td><td>EXECUTIVE SESSION
The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to evaluate the Good Moral Character as required for registration for a pending applicant.</td><td></td><td>CLOSED SESSION</td></tr>
<tr><td>9:45</td><td>IX</td><td>M.G.L. c. 112, § 65C SESSION</td><td></td><td>CLOSED SESSION</td></tr>
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COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION
Boston, Massachusetts, 02114
WebEx Remote Meeting
December 18, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect (leaves 11:00 AM)
Leah Giambarresi, Pharm D, RPh, Secretary
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN
Timothy Fensky, RPh
Katie Thornell, PharmD, RPh (leaves 10:30 AM)
Carly Jean-Francois, RN, NP
Dawn Perry, JD (leaves 10:30 AM)

Board Members Not Present

Patrick Gannon, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh, Director of Investigator
Julienne Tran, PharmD RPh, Investigator
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:03 AM

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting. She explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: K. Tanzer, yes; A. Stein, yes; K. Thornell, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; R. Lopez, yes; T. Fensky, yes; J. Lanza, yes. D. Perry; C. Jean-Francois, yes

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Topic II. **Approval of Agenda** **TIME 8:04 AM**

Agenda 12/18/2020

DISCUSSION:
Change to Agenda:

1. defer Omnicare of Northern MA renovation
2. change minutes to approve from 12/6/20 to 12/4/20

ACTION:
Motion by L. Giambarresi seconded by J. Lanza and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III **Approval of Board Minutes** **TIME: 8:04 AM**

Minutes
1. Draft 12/4/20 Session Minutes

No noted Changes.

Action:
Motion by C. Jean-Francois, seconded S. Hamilton, and voted unanimously to approve the regular session minutes of 12/4/20 with noted changes by roll call vote.

TOPIC IV **APPLICATIONS**

1. The Hilsinger Company Parent LLC WD450 **Transfer of Ownership** **Time: 8:10 AM**

Represented by: Jonathan Costa

Recusal: None

Discussion: The company has changed from a corporation to a LLC and had also undergone a name change. The 2019 reprimand from the MA Board of Pharmacy was in response to the company shipping products to Indiana and North Dakota without proper licensure.

Action: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to approve the transfer of ownership.

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2. Omnicare of Northern MA **Renovation**

Deferred.

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3. Oakmontscript Limited Partnership Wholesale Distributor Time: 8:15 AM

Represented by: None

Recusal: None

Discussion: This wholesaler already has a controlled substance registration through the Drug Control Program but is requesting the Board's license since other states require a Pharmacy Board license in order to do business in their states.

Action: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to approve the application after successful inspection.

TOPIC V FLEX

Pharmacy issues related to COVID-19 and the state of emergency Time: 8:17 AM

Presented by: D. SENCABAUGH

Nothing new to report.

TOPIC VI POLICIES

1. Policy 2020-14: COVID-19 Testing Time: 8:18 AM

Presented by: W. FRISCH

Recusal: None

Discussion: This new policy aligns with the PREP Act that authorizes pharmacists and pharmacy interns to order, administer, process, read, and report the results of FDA-authorized COVID-19 tests. Additionally, the policy authorizes qualified pharmacy technicians to administer and process FDA-authorized COVID-19 tests. Qualified pharmacy technicians are defined as being certified by a Board-approved national certifying body (i.e. ExCPT or PTCB) or having worked at least 500 hours after being licensed as a pharmacy technician.

The policy also outlines requirements to conduct COVID-19 testing as well as follow-up and reporting requirements. A list of specific conditions for conducting such tests on the premises of Board-licensed pharmacies is also included. The Department of Public Health has already approved this document and has been disseminated.

Action: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by roll call to ratify the policy as approved by DPH.

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2. Policy 2020-15: Licensee Scope of Practice **Time: 8:20 AM**

Presented by: W. FRISCH

Recusal: None

Discussion: This document started as a result of public comments received to the Board's draft regulations at 247 CMR 9, Professional Practice Standards. The issue was raised regarding pharmacists practicing independently in the community who are providing professional services to patients in their homes. In discussing the public comment, the Board decided that some of these practice issues would be best handled in a sub-regulatory guidance document.

The intent of this policy is to capture permitted professional activities within the scope of practice of pharmacists, pharmacy interns, and pharmacy technicians and is not intended be an exhaustive list of all professional activities. Since Board policies are "living" documents, this document can be updated as needed to reflect any future practice changes. President-Elect J. LANZA, Board Member T. FENSKY as well as the Advisory Committee to the Board have all had the opportunity to review and provide input.
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Action: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to approve the policy.

TOPIC VII **FILE REVIEW**

Case #1

SA-INV-16782 Trevor Strenchock, PH239322 Time: 08:23 AM

RECUSAL: NONE

DISCUSSION: G. MELTON presented and summarized the investigative report that pertained to these matters.

- BORP was notified by NABP's clearinghouse in July 2020 that Pharmacist Strenchock was disciplined by the Pennsylvania State Board of Pharmacy (Pennsylvania Board). Specifically, Pharmacist Strenchock was disciplined after he failed to properly safeguard controlled substances while he was pharmacy manager of a Pennsylvania pharmacy in violation of recognized standards of pharmacy practice.
- As a result, a technician was able to divert approximately 30,000 units of Schedule II & IV controlled substances over a period of about six months. Pharmacist Strenchock was reprimanded, fined $5,000.00 and required to complete 10 hours of CE in pharmacy law in addition to his annual requirements.
- In his response to BORP, Pharmacist Strenchock admitted that he failed to properly safeguard controlled substances as described in the Pennsylvania complaint. He indicated that he learned a lot from the incident and matured as a pharmacist.
- He described that corrective action was implemented after the discovery of the theft. First, the employee responsible for the diversion was fired. Next, access to functions within the pharmacy software system were password-protected and limited specific to job function only, new protocols

detailing punishment for sharing passwords, and mandatory password changes/updates after a set duration. In addition, a video surveillance system was installed, access to the safe and any controlled substances were limited to pharmacists only, and complete inventory counts were increased from biennial to a monthly basis.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE the matter (SA-INV-16782), No Discipline Warranted.

Case #2
PHA-2020-0058 Walgreens #11688, DS3598 Time: 08:31 AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Untimely RLCS on 8/31/2020 for unknown losses of #176 acetaminophen/codeine 300/30 mg tablets and #63 lorazepam 2 mg tablets discovered on 8/19/2020. The loss of acetaminophen/codeine 300/30 mg tablets was identified during routine cycle counts. When a subsequent decision was made to count all CIII-CVs in the Pharmacy for a baseline inventory, the loss of #63 lorazepam 2 mg tablets was also discovered on 08/19/2020.
- MOR Tran investigated both losses per Walgreens protocol which included the review of systems, recordkeeping, and movement reports; a thorough search of the Pharmacy; and a reconciliation going back to 6/9/2020 when the exact count CIII-CV annual inventory was performed. The cause of the losses could not be determined. MOR Tran speculated the loss of acetaminophen/codeine 300/30 mg could have been due to accidental disposal of a stock bottle, misfilling acetaminophen prescriptions with acetaminophen/codeine 300/30 mg, or previous erroneous adjustments to the inventory in past years. MOR Tran theorized the loss of lorazepam 2 mg may have been due to an unconfirmed over-dispensing of 120 tablets instead of 60 tablets to a patient who receives them monthly with the other 3 tablets due to miscounts.
- Both acetaminophen/codeine 300/30 mg tablets and lorazepam 2 mg tablets were counted weekly for 3 weeks following the discovery of the loss with no additional discrepancies noted. MOR Tran created a recordkeeping log for acetaminophen/codeine 300/30 mg tablets and lorazepam 2 mg tablets which was added to the perpetual inventory binder. The tablets are counted weekly with the balance on hand recorded in the log. Weekly counts of five randomly chosen CIII-CV medications with the balance on hand recorded in the same log was implemented. MOR Tran emphasized with the Pharmacy team the practice of double counting-controlled substances then circling and initialing the quantity printed on the prescription label. A copy of Walgreens SOP "Controlled Substances – Inventory" was provided that was signed and dated by the Pharmacy team acknowledging review.

ACTION: Motion by S. HAMILTON, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2020-0058), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for a period of one year, with special terms to include a monthly exact count of all ACETAMINOPHEN/CODEINE solid dosage forms for 12 months, staff retraining in the areas of inventory

management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days .

Case #3
PHA-2020-0070 CVS #7140, DS89720 Time: 08:36 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

• Untimely RLCS on 9/15/2020 for an unknown loss of #356 lorazepam 1 mg tablets identified on 07/07/2020 via corporate controlled substance monitoring. Once the variance was discovered, CVS Loss Prevention initiated cycle counts of all NDCs of lorazepam 1 mg tablets at the Pharmacy. The reporting was not inclusive of all the required Appendix I information in compliance with BORP Policy 2018-05. Security footage was not reviewed.
• MOR McGrath's explanation of the untimely reporting was the investigation into the loss of lorazepam 1mg was prompted by the Loss Prevention Team and was not initiated by the Pharmacy. No letters of continuation were filed with the DEA or the BORP. The Loss Prevention Team monitored counts and a final reconciliation was completed. MOR McGrath stated at the time of the investigation the NDC in question was no longer stocked by the Pharmacy but the reconciliation report disputed this. The loss was reported under one NDC number but there was a variance of two NDC numbers. According to MOR McGrath, the CVS District Asset Protection Manager felt there may have been a variance between the 2019 and 2020 annual inventory counts which are reconciled at a corporate level despite performing exact counts for both inventories. MOR McGrath responded controlled substances are double counted prior to dispensing per CVS protocols.
• The final reports provided on 09/15/2020 indicated that all loss prevention policies and procedures including diligent inventory management and dispensing standards were reviewed with the Pharmacy team to prevent future losses. Back counting of all narcotics at the time of dispensing to ensure accuracy was also reviewed. A copy of CVS SOP "Federal Regulations and CVS Pharmacy Guidelines for Controlled Substances" which was signed by the Pharmacy team confirming review was submitted.

ACTION: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted by all those present, to refer the matter (PHA-2020-0070), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for a period of one year, with special terms to include a monthly exact count of all BENZODIAZEPINES for 12 months, staff retraining in the areas of inventory management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate and sign off on the BOH report cover page.

Case #4
PHA-2020-0066 Option Care, DS90107 Time: 08:39 AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

• Complaint for failure to timely report above action EM results in Hood 3 (ISO 5) for sampling performed on 9/1/2020 and 9/8/2020 and failure to reduce BUDs of CSPs subsequent to receipt of an above action EM result in the ISO 7 pass through from sampling performed on 10/28/2020 as required.
• On 9/18/2020, an untimely Form 1 (TRG-16911) was submitted for 26 CFU of 3 non-pathogenic organisms identified in a viable surface sample taken on 9/1/2020 in Hood 3. A triple clean was performed and compounding was suspended in Hood 3. Results of the repeat EM performed on 9/9/2020 and received on 9/18/2020 identified 29 CFU including 2 pathogenic organisms in Hood 3 but no notification was sent to the BORP until 10/12/2020. The Pharmacy performed a triple clean and repeat EM was conducted on 09/11/2020. After receiving a passing EM result on 09/18/2020, the Pharmacy resumed sterile compounding in Hood 3. Note, results of the 9/9 sampling and the 9/11 sampling were both received on 9/18/20.
• On 09/21/2020, a Site Visit (ISP-14508) was conducted in response to the AAL reports. A POC was issued for failure to document the triple clean post events and additional documentation was requested. The report noted EM is performed quarterly, every 6 months during certification by EPS and alternately every 6 months internally. Also, additional surface sampling was implemented monthly during COVID. MOR Schreier later clarified the additional sampling is for ISO 5 PECs only. The Pharmacy did not issue a recall as all CSPs were allegedly past expiry and did not perform adverse drug event surveillance.
• On 10/12/2020, an untimely Form 1 was submitted for the second AAL and an untimely combined Form 2 was submitted for both AAL reports. The RCA included temperature and humidity fluctuations; concerns with hand hygiene, aseptic technique, and cleaning of a new compounding technician; installation of Purell dispensers in the cleanroom and negative pressure room on 08/05/2020 by an outside vendor who was not properly garbed; possible contamination with multiple people handling the sampling plates and improper storage of the 09/08/2020 sample (stored upside down). The CAPA included HVAC maintenance, continued EM monitoring, and re-training/re-education of staff on EM, documentation in Simplifi including temperature/humidity monitoring and cleaning tasks, USP 797 bootcamp and USP 797 standards update.
• MOR Schreier responded to the untimely submission of Form 1 and Form 2 for the reported AALs, stating that because Hood 3 was out of commission, the AAL from the repeat EM on 09/08/2020 was considered a continuation of a single event. MOR Schreier did not realize another Form 1 was required and thought everything was due on the POC due date. The decision to not recall CSPs was based on consultation with the corporate clinical services team and that allegedly there would have been only 1-day supply of therapy remaining for CSPs dispensed. Additionally, MOR Schreier indicated that when patients are contacted for deliveries, questions regarding how they are feeling and if there are any issues are routine and had anything been identified, it would have been investigated. Documentation provided showed 42 CSPs with 1-day supply remaining and 31 CSPs with a 2-to-7-day supply of medication remaining on 09/09/2020.
• On 11/09/2020, a timely, third disclosure Form 1 (TRG-17108) was submitted to the BORP after EM performed by EPS on 10/28/2020 identified 8 CFU total of 3 non-pathogenic organisms and 1 pathogenic organism of concern in a viable air sample from the ISO 7 pass through. A triple clean was performed on 11/03/2020 and use of the pass through was suspended until the triple clean was completed. BUDs were not reduced. A timely Form 2 was submitted on 11/27/2020. The RCA included a broken interlock mechanism for the pass through, technicians in street clothes present in the anteroom during EM sampling, and a partially adhered sticker on the pass through. The CAPA included a triple clean of the pass through, use of the pass through was suspended until 11/12/2020 when the retest results showed no growth, and training of cleanroom staff on use of pass through while the interlock was not working. The Pharmacy required that all pharmacy technicians entering the anteroom must wear clean dedicated shoes and clean scrubs changed into on the premises.

• According to MOR Schreier, the pass through is an unclassified area with low or no risk since the workflow is unidirectional from the buffer room to the "dirty" side of the anteroom. As it does not contain a HEPA filter, there is no way to rate the pass through. MOR Schreier stated, "Accordingly, and consistent with industry practice, we treat the pass through as an unclassified space" despite the certification company considering it an ISO 7 space. MOR Schreier provided an attestation to the review and understanding of Board Policy 2019-08.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0066), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 year, with special terms to include:
1. Monthly environmental monitoring (EM) for all ISO-classified spaces (primary and secondary engineering controls) in accordance with the facility's EM sampling plan for the term of probation to include non-viable (particulate) and viable (air and surface) using a two-plate method (general growth media and fungal-specific media). All results, including no growth results, must be provided to the Board's Probation Monitor.
2. Quarterly gloved thumb/fingertip sampling of all compounding personnel for the term of probation. A summary of all results including corrective actions for any failed tests provided to the Board's Probation Monitor.
3. Quarterly media fill qualification for all compounding personnel for the term of probation. A summary of all results including corrective actions for any failed tests provided to the Board's Probation Monitor.
4. An evaluation of the pharmacy's material transfer process (prior to and within the clean room suite) and compliance plan to assure compounding personnel adherence to the company policy. Written report to be provided to the Board's Probation Monitor within 30 days.
5. Engage a qualified third-party professional with expertise in clean room operations and USP <797> / USP <800> to assess all clean room procedures including but not limited to staff training & competency, hand hygiene & garbing, aseptic technique, cleaning & disinfecting, environmental sampling procedures, and policies & procedures. Written report to be submitted to the Board's Probation Monitor within 120 days to include the qualified third-party professional's assessment & recommended corrective actions and registrant's action plan and timeline for implementing said corrective actions.

Topic VIII **EXECUTIVE SESSION** **Time: 9:02 AM**
Read by K. Tanzer

DISCUSSION:
ACTION: At 9:02 AM President K. Tanzer read the statement on reasons for Executive Session.

Topic VIII: **Executive Session** **Time: 9:02AM**

A. Call to Order #1

Motion by, L. GIAMBARRESI, seconded by S. HAMILTON, voted unanimously by roll call to enter executive session.

K. TANZER; yes, S. HAMILTON; yes, R. LOPEZ; yes, S. CORNACCHIO; yes, T. FENSKY; yes, K. THORNELL; yes, D. PERRY; yes; C. JEAN-FRANCOIS, yes., J. LANZA, yes; L. GIAMBARRESI, yes.

Topic IX: **M.G.L. 65 C #1** **Time: 10:17 AM**

A. Call to order #1

DISCUSSION: None
ACTION: President K. Tanzer request a motion to enter M.G.L 65 c Session.

At 10:17 AM J. Lanza, seconded by L. Giambarresi and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

D. Perry Leaves meeting 10:30 AM
K. Thornell Leaves meeting 10:30 AM
J. Lanza Leaves meeting 11:00 AM

Topic X **ADJOURMENT OF MEETING** **TIME: 11:20 AM**

ACTION: Motion by S. Hamilton seconded by C. Jean-Francois, and voted unanimously by those present, to adjourn from General Session by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 12/18/20 General Session
2. Draft Minutes of the 12/4/20 Meeting
3. Applications: The Hilsinger Company Transfer of Ownership WD450
4. Applications: Omnicare of Northern MA Renovation
5. Applications: Oakmontscript Pharma Wholesaler
6. Policy 2020-14: COVID-19 Testing
7. Policy 2020-15 Licensee Scope of Practice
8. SA-INV-16782 Tevor Strenchock PH239322
9. PHA-2020-0058 Walgreens #11688 DS3598
10. PHA-2020-0070 CVS #7140 DS89720
11. PHA-2020-0066 Option Care DS90107

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary